Remarks

Claim rejections – 35 USC 112 second paragraph

Claims 25-37 are pending in the subject application. Claims 25-37 were rejected as being indefinite. Specifically, Examiner objected to the term "the assembly" in claim 25, because there is insufficient antecedent basis for this term in the claim and because it is unclear which elements "the assembly" includes. The term logically relates to the elements recited in the claim that are assembled. Hence, the term is synonymous with the term "device" in this claim. See also the specification on p.16,ln.26-30: "The assembly of the packaging device thus formed contains an unfolded flexible hydrophilic lens ready for use inside the injection support 4, and said lens 1 is bathed in the liquid conserving solution 20 in the flask 19. The whole assembly can be steam-sterilized by placing in an..." Applicant has amended claim 25 by substituting the term "device" for "assembly". Claims 32 and 34 were considered to be indefinite because the meaning of "it" in the limitations "it includes" is unclear. "It" has been replaced in both claims by "the device". Support for these modifications can be found in the specification on p.8,ln.20-23 and p.9,ln.4-8. A similar replacement was made "sua sponte" in claim 35. For support see the specification at p.9,ln.15-18. Regarding the word "unlockable" in claim 35, the qualifier is not necessary (because the claim itself contains a description of the meaning of "unlockable") and, therefore, has been deleted.

By this Amendment, Applicant has amended claims 25, 32, 34, and 35. Entry and consideration of the amendments presented herein is respectfully requested. Favorable consideration of the pending claims is respectfully requested.

Claim rejections – 35 USC 103(a)

Claims 25, 27 and 29 were rejected under 35 USC 103(a) as being unpatentable over Mazzocco (US 4,423,809) in view of Eagles et al. (US 5,616,148).

Examiner argued that Mazzocco "discloses a device for packaging and conserving in a sterile condition a flexible hydrophilic intraocular lens (col.4,ln.33), comprising: an injection support (24); a flexible hydrophilic intraocular lens (23) placed on the injection support (24); a packaging

enclosing at least the lens, injection support and a volume of solution for conserving the lens which bathes the lens and keeps it hydrated, wherein: the injection support (24) is adapted receive and carry the lens flat; the lens is carried flat on the injection support (24) and immersed in a bath of liquid conserving solution contained in a rigid liquid-tight flask (21) which is closed, the assembly is in a sterilized condition (col4,ln.44-63). Mazzocco fails to disclose the injection support including an implantation end through which the lens can be slid and ejected for implantation, said injection support being adapted to be associated with an injection device including a thruster piston able to push the lens toward an implantation end of the injection support and the injection support adapted to carry out folding of the lens prior to the ejection of the lens via the implantation end.

Eagles et al. discloses an injection support (14) which is adapted to receive and carry the lens flat, the injection support including an implantation end (16) through which the lens can be slid and ejected for implantation, said injection support adapted to be associated with an injection device (12) including a thruster piston (18) able to push the lens toward the implantation end of the injection support (Fig.11-12), wherein the injection support is adapted to carry out folding of the lens prior to ejection of the latter via the implantation end (col.4,ln.43-col.5,ln.2) to safely compress the lens for delivery through a small incision in the eye.

It would have been obvious to one of ordinary skill in the art to substitute the injection support of Mazzocco with the injection support (and the associated injection device) of Eagles et al. in order to permit controlled compression of the deformable hydrophilic lens so that it may be inserted through a small incision in the eye."

Mazzocco provides an autoclavable system for packaging of intracellular lens structures (abstract). Commenting on Examiner's understanding of the Mazzocco device, the device does not contain an "injection support". In fact, the device contains a clamp as a fixture which closes around the periphery of (the optical portion of) a lens to maintain a desired orientation of the optical portion of the lens relative to two optically clear surfaces of the outer container and to permit unobstructed observation of the lens from the latter surfaces. The fixture is incapable of serving as an injection

support as its only function is to immobilize the lens in a desired orientation and position relative to two surfaces of the container. Furthermore, the lens is not bathed in liquid primarily to keep it hydrated. (As is explained below, Mazzocco comtemplates the use of both hydrophilic and hydrophobic lenses.) In fact, the Mazzocco device was designed for and serves a different function from that served by the device of the subject invention. "The unique lens packaging system accordingly provides an autoclavable sterile environment for the intraocular lens structure prior to implantation, designed to permit visual inspection and measurement of important optical parameters of the lens structure without removal of the lens from the container" (col.4, ln.25-30). This purpose can also be discovered in the limitations of the claims. Independent claim 1 of patent No. 4,423,809 (Mazzocco) defines a device that comprises "an outer container having at least two optically clear windows arranged in substantially parallel relationship with one another" and "means for receiving and for supporting said intraocular lens structure"... "integrating with said peripheral lens portion of said intraocular lens structure but maintaining said optical zone portion of said intraocular lens structure in a substantially complete visually unobstructed fashion aligned with said outer container windows thereby enabling the intraocular lens structure to be inspected from said outer container windows for prescribed optical parameters of said intraocular lens structure including type, size, configuration, optical finish and diopter power of said lens structure"...

Examiner considers it as obvious to "substitute the injection support of Mazzocco with the injection support (and the associated injection device) of Eagles et al. in order to permit controlled compression of the deformable hydrophilic lens so that it may be inserted through a small incision in the eye." Applicant takes it that Examiner understands "injection support of Mazzocco" to mean Mazzocco's lens holding fixture (24) and the "injection support ... of Eagles et al." the specific embodiment of col.4,ln.33-35. There the "lens cartridge, or a portion of the lens cartridge, is formed as a one-piece unit with the nozzle portion". The devices of Eagles et al. do not include an intraocular lens. The lens is introduced in the "injection support" immediately prior to injector operation, not for storage. See, e.g., the section "Operation" in col.11 & 12. It is further noted that Eagles et al. does not mention hydrophilic lenses. Hence, Examiner proposes that a skilled artisan would somehow pick up on the above-mentioned specific embodiment of Eagles et al. and make a

lens cartridge-nozzle unit, load that unit with a hydrophilic intraocular lens, even though Eagles et al. neither foresees use of a hydrophilic lens nor lens storage in a cartridge, and take this loaded cartridge-nozzle unit to substitute the lens holding fixture in the Mazzocco device to arrive at a device resembling that of the subject invention. Applicant strongly disagrees with this kind of hindsight construction. Furthermore, Examiner is kindly directed to Section 2143.01 (paragraph V) of the MPEP: "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re. Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). As indicated above, the Mazzocco device is characterized in col.4,ln.25-30 as follows: "The unique lens packaging system accordingly provides an autoclavable sterile environment for the intraocular lens structure prior to implantation, designed to permit visual inspection and measurement of important optical parameters of the lens structure without removal of the lens from the container". Hence, a key function of the Mazzocco device is to "permit visual inspection and measurement of important optical parameters of the lens structure". This requires, as is specified in claim 1, "maintaining said optical zone portion of said intraocular lens structure in a substantially complete visually unobstructed fashion aligned with said outer container windows..." If as proposed by the Examiner a lens would be introduced that is contained in, but not fixedly associated with, a lens cartridge-nozzle piece, it would not be present in the outer container in a "visually unobstructed fashion" and would not be maintained "aligned with said outer container windows". Accurate assessment of lens characteristics and lens optical parameters could not be achieved in an unobstructed fashion as required by Mazzocco through a cartridge made from a plastic, or even steel or titanium (Eagles et al.,col.6,ln.39-42), especially if the lens is not maintained in alignment with the container's optical windows. Hence, the modification suggested by the Examiner would render the prior art (Mazzocco) device "unsatisfactory for its intended purpose". Examiner is respectfully requested to withdraw her rejection of claims 25, 27 and 29 under 35 USC 103(a) as being unpatentable over Mazzocco (US 4,423,809) in view of Eagles et al. (US 5,616,148).

Claims 26 and 28 were rejected under 35 USC 103(a) as being unpatentable over Mazzocco (US 4,423,809) in view of Eagles et al. (US 5,616,148) as applied to claim 25 above, and further in view

of Bazell et al. (US 3,930,580).

As discussed before, Examiner's proposal to recreate a device that resembles that of the subject invention by modifying the device of Mazzocco through substitution of an essential element with other elements, including an element from Eagles et al., is improper for two reasons. First, it is based on hindsight construction. Second, the proposed modification would so alter the Mazzocco device that it would be unfit for its intended purpose. Consequently, there was no suggestion or motivation to make the proposed modification, and the proposed modification cannot serve as a basis for an obviousness-type rejection. This argument not only applies to independent claim 25 but also to all claims dependent from claim 25, including claims 26 and 28. Examiner is respectfully requested to withdraw her rejection of claims 26 and 28 under 35 USC 103(a) as being unpatentable over Mazzocco (US 4,423,809) in view of Eagles et al. (US 5,616,148) as applied to claim 25 above, and further in view of Bazell et al. (US 3,930,580).

Claims 25,27 and 30-33 were rejected under 35 USC 103(a) as being unpatentable over Eagles et al. (US 5,616,148) in view of Mazzocco (US 4,423,809) and Feingold et al. (US 5,728,102).

Rejection of claims 25 and 27 is not proper under Eagles et al., because these claims do not relate to a "surgical device for implantation of a deformable intraocular lens". They relate to a device for storage and packaging of a hydrophilic lens in a sterile condition. Hence, the argument presented regarding to these claims under a reversal of references is in fact the same as that discussed previously. Consequently, the rejection as it relates to these claims should be withdrawn for the reasons discussed before.

Regarding claims 30-33, Examiner summarized her argument in the following statement: "In configuring the device of Eagles et al. to deliver a hydrophilic lens, it would have been obvious to one of ordinary skill in the art to maintain at least the lens and the injection support in the conserving solution inside a rigid flask as suggested by Mazzocco in order to permit inspection of the optical parameters of the lens without removal of the lens from the injection support." As a first step in a series of modifications by which Examiner suggested a skilled artisan would arrive at the invention of claims 30-33, Examiner proposed that "it would have been obvious to one of ordinary skill in the

art to replace the lens in the device of Eagles et al. with the flexible hydrophilic lens of Mazzocco since the lens of Mazzocco provides the advantage of being able to return to its original shape, size and focal length after deformation of the lens and insertion into the eye." Regarding "the lens of Mazzocco", Examiner asserted that "Mazzocco discloses the flexible hydrophilic lens has memory characteristics which enable the lens to be deformed during delivery and then return to its original configuration, full size and fixed focal length after insertion into the eye (col.2,ln.3-17 and col.7,ln.27-32 of US Patent 4,573,998 which is incorporated by reference in col.1,ln.7-12 and col.4,ln.31-35)." This reading of US Patent No. 4,573,998 is incorrect. Col.2,ln.3-17 discusses flexible lenses in general and does not distinguish hydrophilic and hydrophobic lenses. Hence, the discussion of memory characteristics of flexible lenses applies to different types of flexible lenses, at least to the types described in the patent. Specific lens materials considered in US 4,573,998 are enumerated in col7,ln.27-32. The materials disclosed can be used to make hydrophobic (e.g., silicon elastomers) as well as in hydrophilic lenses. Because space memory is an attribute of both hydrophilic and hydrophobic lenses, Examiner's rationale for associating a hydrophilic lens with the device of Eagles et al. fails.

For sake of discussion only, even if the skilled artisan somehow had a motivation to associate a hydrophilic lens with the device of Eagles et al., Examiner's argument why the artisan would be motivated to maintain at least the lens and the injection support in the conserving solution inside a rigid flask as suggested by Mazzocco fails because, as discussed before, introduction of a lens loosely contained within an injection support would no longer "permit inspection of the optical parameters of the lens without removal of the lens from the injection support" and flask.

The further argument based on Feingold et al. does not need to reached because its operation is based on the availability of a device according Eagles et al. comprising as a separate element an injection support-nozzle piece loaded with a hydrophilic lens contained in a solution inside a rigid flask. As discussed before, Examiner failed to show why a skilled artisan was motivated to produce such a device. The same argument applies to the rejection of claim 34 under 35 USC 103(a) as being unpatentable over Eagles et al. in view of Mazzocco and Feingold et al as applied to claim 33 above,

and further view of Figueroa et al. Examiner is respectfully requested to withdraw the rejections.

Claims 25, 27, 30, 31, 35, and 36 were rejected under 35 USC 103(a) as being unpatentable over Figueroa et al. (US 5,873,879) in view of Mazocco (US 4,423,809).

Figueroa describes and claims

"1. A device for inserting a flexible intraocular lens having an optic portion and a haptic portion into an eye, said device comprising:

a tubular member including a passage for receiving a lens, said passage having an open distal end for inserting the lens into an eye and a staging area for supporting the lens in a substantially unstressed state, said staging area including proximal and distal supporting surfaces for supporting the haptic portion of the lens so that the optic portion of the lens is suspended to substantially avoid contact of the optic portion with interior portions of said tubular member in said substantially unstressed state; and

a plunger being movably received within said passage of said tubular member for moving the lens through said open distal end of said tubular member and into the eye."

Examiner observed that "Figueroa et al. fail to disclose a hydrophilic lens and a packaging enclosing at least the lens, the injection support and a volume liquid solution which bathes the lens and keeps it hydrated." Examiner argued "Mazzocco discloses the flexible hydrophilic lens has memory characteristics which enable the lens to be deformed during delivery and then return to its original configuration, full size and fixed focal length after insertion into the eye (col.2,ln.3-17 and col.7,ln.27-32 of US Patent 4,573,998 which is incorporated by reference in col.1,ln.7-12 and col.4,ln.31-35). It would have been obvious to one of ordinary skill in the art to replace the lens in the device of Figueroa et al. with the flexible hydrophilic lens of Mazzocco since the lens of Mazzocco provides the advantage of being able to return to its original shape, size and focal length after deformation of the lens and insertion into the eye." Examiner misread Mazzocco. Col.2,ln.3-17 discusses flexible lenses in general and does not distinguish hydrophilic and hydrophobic lenses. Hence, the discussion of memory characteristics of flexible lenses applies to different types of flexible lenses, at least to the types described in the patent. Specific lens materials considered in US

4,573,998 are enumerated in col7,ln.27-32. The materials disclosed can be used to make hydrophobic (e.g., silicon elastomers) as well as in hydrophilic lenses. Because space memory is an attribute of both hydrophilic and hydrophobic lenses, Examiner's rationale for associating a hydrophilic lens with the device of Figueroa et al. fails. Regarding the packaging of the hydrophilic lens, Examiner argued that "In configuring the device of Eagles et al. to deliver a hydrophilic lens, it would have been obvious to one of ordinary skill in the art to maintain at least the lens and the injection support in the conserving solution inside a rigid flask as suggested by Mazzocco in order to permit inspection of the optical parameters of the lens without removal of the lens from the injection support." It is assumed that this sentence was meant to relate to a device of Figueroa and not a device of Eagles. Examiner's suggestion why the artisan would have been motivated to maintain at least the lens and the injection support in the conserving solution inside a rigid flask of Mazzocco fails because, as discussed before, introduction of a lens loosely contained within an injection support would no longer permit inspection of the optical parameters of the lens without removal of the lens from the injection support and flask. If there is not motivation for one to store a hydrophilic lens-containing injection support in a liquid-filled rigid flask of Mazzocco, the question does not need to be addressed whether it would be obvious to configure an arrangement whereby the flask of Mazzocco could be joined to the body of an injector. Examiner is respectfully requested to withdraw the rejection.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

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